

Application No. 10/082,003
Amtd. dated December 9, 2005
Reply to Office Action of July 14, 2005

REMARKS

Applicants submit this Amendment in response to the Examiner's Final Office Action mailed July 14, 2005 and Applicants' in-person interview with Examiner Micah P. Young on December 7, 2005. Claims 6, 8-10, 15-19 and 22 are cancelled without prejudice. Claim 11 is amended. Support for the amended claim language appears in the Specification, for example, at page 26, lines 10-11, and lines 28-29. Claims 1-5, 7, 11-14 and 20-21 are now pending. Reconsideration is respectfully requested in view of the following amendments and remarks.

Applicants express appreciation to the Examiner for conducting an in-person interview with Applicants on December 7, 2005. During the interview, Applicants distinguished the claimed invention with the combined disclosures of Wall et al. (U.S. Pat. No. 6,288,072) and Comins et al. (U.S. Pat. No. 5,162,532). These two references have been cited by the Examiner in the rejection of claims 1-5, 7 and 11-21 under 35 U.S.C. §103(a).

As agreed during the interview, Comins et al. not only fails to disclose the claimed crystal form D of 9-nitro-camptothecin (9NC) having the particular spectral characteristics specified in claim 1, but also fails to disclose how to prepare such a crystal form of 9NC by **recrystallization in acetonitrile** as specified in claims 7 and 20. In contrast, as pointed out by Applicants to the Examiner, Comins et al. merely discloses using solvent such as tetrahydrofuran and acetonitrile in the **synthesis of pyridone intermediates** of formula III (column 3, lines 45-49). In fact, in the synthesis of the final product, (\pm)-camptothecin (a different compound from 9NC), the yellow solid of the product was purified by using silica gel and 4% $\text{CH}_3\text{OH}/\text{CHCl}_3$ (column 12, lines 11-14). Thus, this reference neither teaches the claimed crystal form D of 9NC nor contains enabling disclosure of how to prepare the claimed crystal of 9NC.

On the other hand, Wall et al. is even further away from disclosing the claimed invention. This reference does not even disclose 9NC; rather, it discloses 9-nitro-10,11-methylenedioxy-20-O- β -ala-lys-20-(S)-camptothecin (column 5, lines 49-50) and 9-nitro-20-O- β -ala-20-(S)-camptothecin (column 6, line 15).

In view of failure of the cited references, each alone or in combination, to teach every elements of independent claims 1 and 11, a *prima facie* case of obviousness has not been established under 35 U.S.C. §103(a). Withdrawal of the ground of rejection is therefore respectfully requested.

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CONCLUSION

In view of the above amendment and remarks, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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